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26646	7590	07/18/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			VALENROD, YEVGENY	
			ART UNIT	PAPER NUMBER
			1621	
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Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species: Forms B, L, P, S, U, alpha, delta, and form sigma of nateglinide. The species are independent or distinct because each form has different characteristics when examined by Differential Scanning Colorimetry (DSC), Fortier Transfer Infra Red spectroscopy (FTIR) and X-ray powder diffraction. In addition, each form requires a unique method of making.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1621

2. During a telephone conversation with Payam Moradian on June 12 2006 a provisional election was made with traverse to prosecute the invention of Form U of nateglinide, claims . Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-40 and 55-96 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Provisional Double Patenting***

#### ***Statutory***

3. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 101 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has FTIR peaks at 3350, 1701, 1646 and 1291 cm<sup>-1</sup>, (see Figure 31) same as recited in claim 101 of Application No. 10/693166. If the applicant alleges that the product results from a different process, it is the examiners position that process by which the

Art Unit: 1621

product was made is not a sufficient difference to make the alleged different products patentably distinct.

4. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 102 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has FTIR identical to the one recited in claim 102 of Application No. 10/693166 (see Figure 31 of the instant application and Figure 31 of the Application No. 10/693166). If the applicant alleges that the product results from a different process, it is the examiners position that process by which the product was made is not a sufficient difference to make the alleged different products patentably distinct.

5. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 97 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has peaks at: 3.8, 4.8, 7.5, 13.8 and 17.00 (figure 17) as is claimed in the claim 97 of Application No. 10/693166.

6. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 97 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in

Art Unit: 1621

fact been patented. In the instant application, form U has XRPD pattern represented by figure 17, said pattern is substantially depicted in Figures 65-68 of Application No. 10/693166.

7. Claim 53 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10/746697. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has XRPD pattern represented by figure 17, said pattern contains peaks at: 4.6, 7.4, 13.8 and 17. The instant and the reference application are therefore applications, which are concerning the preparation of the same Form of nateglinide. Claim one of the reference application claims preparation of a specific form of nateglinide, which is characterized by the XRPD peaks as listed above. The said form is prepared by: preparing a solution in ethyl acetate, seeding the solution with nateglinide crystals, and recovering the crystalline form as a precipitate. Instant claim 53 recites the same steps for preparing Form U. Since all the limitations of claim 53 are met by claim 1 of the co-pending application #10/746697, claim 53 is rejected under provisional double patenting.

*Non-statutory/obviousness type*

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude"

Art Unit: 1621

granted by a patent and to prevent possible harassment by multiple assignees.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 97 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 97 and 98

Art Unit: 1621

of copending Application No. 10/693166. Although the conflicting claims are not identical, they are not patentably distinct from each other because the XRPD pattern of Form U in the instant application has peaks at: 4.8, 7.5, 13.8 and 17.00 (figure 17) as is claimed in the claim 97 of Application No. 10/693166. There is also a peak at 3.8, which although reduced, is also present in the reference application. The term "substantially reduced" used in claim 97 of the reference application, does not render the invention patentably distinct from instant the claim 97.

The same peaks (4.8, 7.5, 13.8 and 17.00) show up in the XRPD pattern of Figures 65-68 of No. 10/693166. Compared to Figure 17 of the instant application, the location of the peaks in Figures 65-68 of No. 10/693166 is identical, however, the intensity of the peaks slightly varies. Nonetheless, the difference in the XRPD patterns is not sufficient to render the crystalline forms represented by the said XRPD patterns patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Rejection 35 USC 112***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.



10. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for seeding the solution with form B, does not reasonably provide enablement for seeding with a crystal of any other form of nateglinide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Although the process of seeding a solution with a crystal in order to facilitate crystallization is well known in the art, in the instant application the said process includes embodiments that would not be obvious to a person of ordinary skill. Particularly, seeding the solution with a crystal of Form B in order to obtain crystals of form U. While seeding with form B furnishes the desired product form U, there is a great deal of uncertainty when one considers utilizing the other 25 forms of nateglinide for seeding with intent to obtain Form U. Determining which of the other forms, if any, are capable of furnishing form U would require undue experimentation on the part of the one wishing to practice the invention. The matter is further complicated by the fact that crystallization conditions such as temperature and cooling rates often have an effect which form of nateglinide is obtained (see the table in the specification on pages 19-20)

11. Claims 41-49 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements of the process such as temperatures at which each individual step is performed, duration of stirring the

Art Unit: 1621

solution, solvent/anti-solvent ratio and relative temperatures, pH of the solution, temperature and pressure at which the product is dried are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Formulations of Nateglinide are readily converted from one form to another by heating. Also, obtaining the various forms of nateglinide is achieved by varying temperature and crystallization/precipitation procedures. Without providing the exact conditions required to make the specific form, in this case form U, one of ordinary skill in the art would have to perform undue experimentation in order to practice the claimed invention. For example, merely stating "crystallizing nateglinide form U from the solution" as applicant does in claim 41 part "b" does not provide adequate guidance as to how one should practice the invention. In the specification on page 17 line lines 16-22, applicant discusses the effects of solvent/anti-solvent on the form of nateglinide obtained via crystallization. In the same paragraph the effects of prolonged crystallization are discussed.

According to the applicant: Form E can be obtained from toluene/methanol mixture, Forms B and Z are recovered from heptane/ethyl acetate mixture and forms B and H are obtained from toluene/ethyl acetate. Claim 49 contains the strictest limitations of the claims that depend directly or indirectly on claim 41. Yet, even claim 49 fails to provide adequate guidance. The claim states that the product should be recovered before its transition to another form, but does not provide any limitation on the time it takes for the product to undergo the said transition.

12. Claims 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The temperature and the duration of crystallization are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). On pages 19-20 the applicant provides a table of conditions and forms of nateglinide obtained as a result of applying a given set of conditions. From Entry 4 on page 20, one can see that by merely stirring the solution after crystallization various forms can be form obtained. For example: H is obtained directly after crystallization, U after stirring for 1-5 hr. and  $\delta$  after stirring for more than 5 hr. To enable the disclosure of these claims applicant needs to include the limitations, which would allow one skilled in the art to practice the invention without unnecessary experimentation. These limitations include: ranges that would define the terms "suited temperature" and "sufficient amount of time".

13. Claims 53-54 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Temperature at which crystallization occurs, the cooling rate of the nateglinide solution, and duration of crystallization are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). On p 18 lines 13-21 of the disclosure, the applicant describes conditions that are favorable for formation of form U. These conditions

Art Unit: 1621

include: stirring for about 1 hour, but no more than 5 hours; crystallization and filtering temperatures of -15 to 10°C, starting with a temperature of 25-35°C followed by cooling in 1 hour to -15 to 10°C. These or other limitation that find support in the specification should be included in the claim language.

### ***Drawings***

The drawings are objected to because Figure 31, which pertains to the elected specie, has a peak at 1536 that is left of the peak at 1537. The said positioning of the signals is a physical impossibility in IR spectroscopy because the wave numbers increase from right to left, not the other way around. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

Art Unit: 1621

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Conclusion***

Claims 1-97 are pending in the application

Claims 1-40 and 55-96 are withdrawn from further consideration.

Claims 41-54 and 97 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

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